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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/785,326	02/24/2004	Fredric J. Cohen	X-11057C	9685

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EXAMINER
ANDERSON, JAMES D

ART UNIT	PAPER NUMBER
1614	

NOTIFICATION DATE	DELIVERY MODE
04/11/2008	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patents@lilly.com

Office Action Summary	Application No.	Applicant(s)	
	10/785,326	COHEN ET AL.	
	Examiner	Art Unit	
	JAMES D. ANDERSON	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 January 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *19 and 145-156* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *19 and 145-156* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *1/25/2008*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 19 and 145-156 are presented for examination

Applicants' amendment filed 1/25/2008 has been received and entered into the application. Accordingly, no claims are amended, cancelled, or added.

Applicants' arguments have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous Office Actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Information Disclosure Statement

Receipt is acknowledged of the Information Disclosure Statement filed 1/25/2008. The references cited therein have been considered to the extent that each is a proper citation. Please refer to the attached USPTO Form 1449.

Response to Arguments

Applicant's arguments filed 1/25/2008 have been fully considered but they are not persuasive.

Firstly, Applicants argue that there is no discussion in Black about diagnosing or screening patients, who are to be administered raloxifene for osteoporosis, for breast cancer risk reduction or prevention. Applicants submit that there is no teaching or expectation that women who are so diagnosed represent all post-menopausal women. However, the Examiner respectfully submits that all post-menopausal are naturally in need of a reduction in the

likelihood that they will incur or develop estrogen-dependent breast cancer because all women are at risk of developing breast cancer. While it is certainly true that this risk is greater in some women than in others, the fact remains that any woman having breast tissue is at some risk of developing breast cancer. As such, the limitation "diagnosed as being in need of such therapy" does not distinguish the claims from the teachings of Black.

Secondly, Applicants argue that the present application defines "about 60 mg" to "encompass 55 to 65 mg of raloxifene hydrochloride" and thus "about 60 mg" does not encompass any effective amount. However, while it is true that Applicants state that about 60 mg encompasses 55 to 65 mg, this definition does not limit the amount of raloxifene to 55 to 65 mg; it only indicates that 55 to 65 mg is *encompassed by* "about 60 mg". Such a teaching does not limit "about 60 mg" to only a range of 55 to 65 mg as suggested by Applicants.

Accordingly, the Examiner is not persuaded that the claimed methods are not inherently taught by Black who teaches administration of the same compound to the same patient population in amounts that are clinically effective. The rejection is maintained for the reasons of record and as reiterated below.

With respect to the 35 U.S.C. 103 rejection of claim 19, the Examiner refers to the discussion above as Applicants have presented no arguments specific to this rejection.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 145-156 are again rejected under 35 U.S.C. § 102(b) as being anticipated by **Black *et al.*** (U.S. Patent No. 5,393,763; Issued Feb. 28, 1995).

The instant claims recite a method of reducing the likelihood of incurring or developing estrogen-dependent breast cancer in a post-menopausal woman comprising administering raloxifene. Dependent claims recite the limitation wherein the woman is also diagnosed as having established osteoporosis.

Black *et al.* provides methods for inhibiting the loss of bone and are thus effective for the treatment of osteoporosis (Abstract). One of the most common types of osteoporosis is found in post-menopausal women (col. 1, lines 34-35). The methods of the invention comprise administering an effective amount of a compound of formula I as recited in column 2, lines 25-59. Such compounds include raloxifene as instantly claimed (cols. 7-8 and Examples). Doses of 0.1 to 1000 mg and more typically from about 200 to 600 mg are administered (col. 6, line 68 to col. 7, line 5). The instantly claimed dose is "about 60 mg". The "about" modifier expands the range of raloxifene that can be administered to a patient to reasonably include any effective amount, including those doses recited in Black *et al.* In the examples provided in the reference, raloxifene is administered to "post-menopausal women" (col. 19, lines 15-16 and claim 3), thus teaching the instantly claimed patient population. Claim 2 of the '763 patent recites patients suffering from osteoporosis as instantly claimed in claims 153-156.

It is noted that *In re Best* (195 USPQ 430) and *In re Fitzgerald* (205 USPQ 594) discuss the support of rejections wherein the prior art discloses subject matter, which there is reason to believe inherently includes functions that are newly cited, or is identical to a product instantly

claimed. In such a situation the burden is shifted to the applicants to "prove that subject matter to be shown in the prior art does not possess the characteristic relied on" (205 USPQ 594, second column, first full paragraph). There is no requirement that a person of ordinary skill in the art would have recognized the inherent disclosure at the time of invention, but only that the subject matter is in fact inherent in the prior art reference. *Schering Corp. v. Geneva Pharm. Inc.*, 339 F.3d 1373, 1377, 67 USPQ2d 1664, 1668 (Fed. Cir. 2003); see also *Toro Co. v. Deere & Co.*, 355 F.3d 1313, 1320, 69 USPQ2d 1584, 1590 (Fed. Cir. 2004) ("[T]he fact that a characteristic is a necessary feature or result of a prior-art embodiment (that is itself sufficiently described and enabled) is enough for inherent anticipation, even if that fact was unknown at the time of the prior invention").

In the instant case, it flows from the teachings of Black *et al.* that patients being treated with raloxifene so as to inhibit bone loss will naturally have a reduced likelihood of developing breast cancer. It is clear that Black *et al.* contemplate treating post-menopausal women with raloxifene and further contemplate treating patients having osteoporosis with raloxifene (*i.e.*, the same patient populations as instantly claimed). Because the same patient populations are being treated with the same drug, the instantly claimed result of such treatment would naturally occur in the patients being treated in the '763 patent.

Accordingly, the claims are deemed properly rejected as being anticipated by Black *et al.* Applicants' discovery of an additional, unappreciated result of treating post-menopausal women with raloxifene is not patentable over the '763 patent.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. § 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR § 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. § 103(c) and potential 35 U.S.C. § 102(e), (f) or (g) prior art under 35 U.S.C. § 103(a).

Claim 19 is again rejected under 35 U.S.C. § 103(a) as being unpatentable over **Black *et al.*** (U.S. Patent No. 5,393,763; Issued Feb. 28, 1995) as applied to claims 145-156, *supra*.

Black *et al.* disclose as applied *supra*. The reference does not explicitly disclose the instantly claimed administration for at least six months. However, in the absence of a showing of unexpected results, it would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to administer raloxifene for as long was necessary to inhibit bone loss as disclosed in Black *et al.* As such, because the same patient population is being administered the same active agent, it flows from the disclosure of Black *et al.* that such extended treatment will lead to a reduced likelihood of incurring or developing estrogen-dependent breast cancer in post-menopausal women.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JAMES D. ANDERSON whose telephone number is (571)272-9038. The examiner can normally be reached on MON-FRI 9:00 am - 5:00 pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/James D Anderson/
Examiner, Art Unit 1614

/Ardin Marschel/
Supervisory Patent Examiner, Art Unit 1614